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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/216,242	12/18/1998	JOHN M. LIPARI	6439.US.O1	1025

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STEVEN F. WEINSTOCK; ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/216,242

Applicant(s)

Lipari

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 6, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 12, and 14-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 12, and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment dated 7-28-02, supplemental response dated 8-6-02 and the change of address dated 11-7-02 are acknowledged.

Claims included in the prosecution are 1, 3-5, 12 and 14-17.

Claim Rejections - 35 U.S.C. § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 1, 3-5, 12 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lacy (5,645,856).**

Lacy discloses capsules containing solutions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again center around 'structured lipid'. These arguments have been extensively addressed before. The examiner points out that the claim language is given the broadest reasonable interpretation (see MPEP 2182). It would appear that in the art that the term, 'structured lipids' is given different interpretation and

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therefore, the interpretation given the references of Chavkin, and Kikuchi is still pertinent since instant claims do not recite the specific lipids which applicant considers as structured lipids. According to applicant, capric and/or caprylic triglycerides taught by Lacy are not structured lipids (examiner also refers to the examiner's reasoning in the previous action in this context).

Applicant argues that instant claims now recite 'consisting of' and therefore, excludes the surfactants. Applicant further argues based on teachings of Lacy on col. 3, lines 41-42 that instant invention does not exhibit or demonstrate the property of 'not substantially inhibiting the lipolysis of the oil. These arguments are not found to be persuasive since as pointed out before, instant specification clearly indicates that surfactants can be added (see example 1 in instant specification); in fact, it would appear from the comparison between figure 1 and figure 2, the plasma concentrations of fenofibrate are higher in the presence of surfactant than without it. Applicant has not shown any unexpected results by not including the surfactant as suggested by Lacy as argued.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1, 3-5, 12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy cited above, further in view of Babayan (4,952,606) of record, Bistraian (4,871,768), Hyltander (NCP, 1995) of record, individually or in combination.

Lacy as pointed out above, discloses capsules containing solutions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglycerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7). It is deemed obvious to one of ordinary skill in the art Lacy also does not teach omission of a surfactant. However, in the absence of showing unexpected results, it is deemed obvious to one of ordinary skill in the art not to include a surfactant if it is deemed to be not necessary.

Babayan teaches that structured lipids do not elevate cholesterol levels when administered (col. 1, lines 43-50).

Bistraian teaches that structured lipids assist in fighting atherosclerotic problems (col. 3, line 64 through col. 4, line 15).

Hyltander discusses the advantages of the structured lipids and emulsions containing these in clinical practice (pages 92-96).

Assuming that Lacy's triglycerides are not structured lipids, it is deemed obvious to one of ordinary skill in the art to use the structured triglycerides instead of the triglycerides taught by Lacy, especially when the drug used is for regulating cholesterol or

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lipid metabolism, since structured triglycerides have advantages relating to cholesterol and atherosclerosis and other clinical advantages as taught by Babayan, Bistraian and Hyltander respectively.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Lacy have been addressed above. Applicant argues that Babayan, Bistrian and Hyltander do not disclose fibrates and the solubility of fibrates in structured lipids. This argument is not found to be persuasive since references which teach the advantages of using structured lipids when the goal is cholesterol regulations provide motivation for one use the structured lipids.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

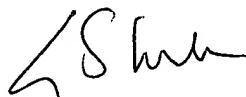
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a

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properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 15, 2002